

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau(43) International Publication Date
21 April 2005 (21.04.2005)

PCT

(10) International Publication Number
WO 2005/034741 A1(51) International Patent Classification⁷: A61B 5/00(21) International Application Number:
PCT/US2004/024393

(22) International Filing Date: 28 July 2004 (28.07.2004)

(25) Filing Language: English

(26) Publication Language: English

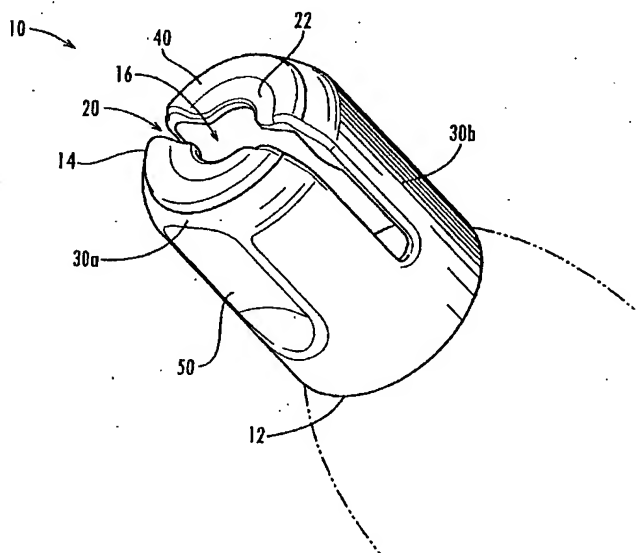
(30) Priority Data:
60/503,910 18 September 2003 (18.09.2003) US(71) Applicant (for all designated States except US): FACET
TECHNOLOGIES, LLC [US/US]; 1850 Parkway Place,
Suite 900, Marietta, GA 30067 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): FLYNN, Stephen
[US/US]; 605 Wheatleigh Curve, Peachtree City, GA
30269 (US). LEVAUGHN, Richard, W. [US/US]; 532
Sullivan Road, Newnan, GA 30265 (US). RUF, Christo-
pher, J. [US/US]; 2120 Ithica Drive, Marietta, GA 30067
(US). KENNEDY, Gwenn, E. [US/US]; 5 North Lakeside
Drive, Ellenwood, GA 30294 (US). LIPOMA, Michael,V. [US/US]; 4066 Argonne Court, Villa Rica, GA 30180
(US). SALLERAS, Juan, D. [US/US]; 14430 Wyndham
Farms Drive, Alpharetta, GA 30004 (US). HOLZA-
EPFEL, Jac [US/US]; 106 Fen Way, Peachtree City, GA
30269 (US). RAMOS, Sylvia [US/US]; 1850 Parkway
Place, Suite 900, Marietta, GA 30067 (US).(74) Agent: GROFF, Bradley, K.; Gardner & Groff, PC, Paper
Mill Village, Building 23, 600 Village Trace, Suite 300,
Marietta, GA 30067 (US).(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,

[Continued on next page])

(54) Title: LANCING DEVICE END CAP WITH SKIN-ENGAGING JAWS



(57) Abstract: An endcap for a lancing device, the endcap (10) comprising a contact face (22) for contact with the skin around a sampling site, and a slot (20) across the contact face (22) to form an opposed pair of jaws (30a,b) that can be pinched toward one another and will resiliently spring back apart when released, thereby alternately pinching and tensioning tissue around the sampling site to enhance sample collection and prevent premature wound closure.



GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

LANCING DEVICE END CAP WITH SKIN-ENGAGING JAWS

Cross-Reference to Related Application

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 60/503,910, filed September 18, 2003, the entirety of which is hereby incorporated herein by reference for all purposes.

Technical Field

[0002] The present invention relates generally to medical devices and procedures, and more particularly to lancing devices for sampling blood or other bodily fluids. The invention more particularly relates to an end cap for use in conjunction with a lancing device that allows for the collection of an increased volume of blood or bodily fluid to be sampled.

Background of the Invention

[0003] Many medical procedures require puncturing of the skin, and sometimes underlying tissues, of a human or animal subject. For example, a sharp lancet tip is commonly used to puncture the subject's skin for sampling of blood or other body fluid, as for example in blood glucose monitoring by diabetics. Generally, lancet blades or needles are much thinner than traditional hypodermic syringe needles, and therefore result in less pain to the patient. A lancet having a sharp lancing tip typically is mounted, permanently or releasably, to the drive mechanism of a lancing device. The drive mechanism includes one or more springs, cams, motors, or other mechanism(s) for moving the lancing tip from a retracted position shielded within a housing of the lancing device to an extended position outside of the housing for lancing the subject's skin. The lancing device may also include a cocking mechanism for arming the drive mechanism, and/or a triggering mechanism for firing the device. The housing of the lancing device typically includes an endcap with an opening through which the lancing tip extends in its extended position. The endcap may

be releasably or permanently attached to the remainder of the housing, or can comprise an integral part of the housing.

[0004] One common problem that has been found to exist with many known lancets and lancing devices is the closure of the puncture site before an adequate volume of blood has been collected. Premature closure of the puncture requires additional blood to be drawn from the patient, often in a separate and sometimes less desirable location, resulting in an increase in pain and stress to the subject. Costs also increase, as multiple lancets are required to acquire an adequate sample. This is particularly the case when alternate sampling sites other than the fingertips, such as for example the forearm or earlobe, are lanced. Lancing at such alternate sampling sites may be desirable because repeated lancing of the fingertips can result in callous formation, leading to less consistent sampling and decreased sensitivity of the fingertips. In addition, the fingertips have a greater density of nerve endings than alternate sampling sites, resulting in greater pain sensation from fingertip lancing than lancing at alternate sites. To increase patient compliance with a prescribed sampling regimen, it is desirable to minimize pain resulting from the lancing operation. However, because alternate sites typically contain a lower density of capillaries or a deeper capillary bed than the fingertips, alternate sampling sites often yield insufficient sample sizes or are prone to premature closure.

[0005] Attempts have been made to provide lancing devices that inhibit premature closure of the puncture site and yield increased sample size. Such attempts have included the use of a stimulator member slideably mounted to the housing for cyclically pumping around the puncture site to "milk" the wound. Although utilizing the aforementioned pumping sequence may allow a larger sample to be collected before closure of the puncture site, occasionally a sample is still insufficient, and another lancing operation to collect blood or analytic fluid is required. Additionally, the repeated application and release of pressure from such pumping can result in contact between the sample and the lancing device, smearing and/or contaminating the sample and necessitating another lancing

operation, and/or can lead to bruising of the tissue surrounding the sampling site. Also, the provision of a translationally mounted stimulator member results in increased complexity and cost of the lancing device.

[0006] Thus it can be seen that needs exist for improved lancing devices and methods to facilitate increased sample volume of blood or other analytic fluid, and to prevent premature closure of the sampling site. Needs further exist for such mechanisms and methods that are readily adaptable to current lancing devices and procedures, and which can be utilized for lancing at fingertip as well as alternate sample collection sites.

Summary of the Invention

[0007] In example forms, the present invention is an endcap for a lancing device that enables collection of an increased volume of blood or other body fluid to be sampled from a sampling site of a human or animal subject. The device of the present invention is suitable for use at fingertip sampling sites, but is also well suited for use at alternate sampling sites such as the forearm and/or earlobe. In further embodiments, the invention is a sampling method for increasing collected sample size of blood or other body fluid from a sampling site.

[0008] In one aspect, the present invention is an endcap for a lancing device. The endcap preferably has a first end for connection to the lancing device and a second end including an opening for passage of a sharp tip portion of a lancet. The endcap preferably further includes a contact face around the opening and a slot extending through the contact face, the slot separating at least the second end of the endcap into an opposed pair of jaws.

[0009] In another aspect, the invention is a lancing device for collecting a sample of body fluid from a sampling site on the skin of a subject. The lancing device preferably includes a lancet and a housing comprising an endcap, the lancet being movable between a first position within the housing and a second position wherein at least a sharp tip portion of the lancet extends through the endcap. The endcap preferably has first and second

opposed jaws movable between an unbiased position wherein the jaws are spaced a distance apart from one another, and a biased position wherein the jaws are squeezed toward one another.

[00010] In still another aspect, the invention is a method of lancing skin to collect a fluid sample, the method preferably including the steps of placing a contact face of a lancing device against a subject's skin at a sampling site, the contact face having first and second portions separated by a slot; lancing the skin at the sampling site; and pinching the first and second portions of the contact face toward one another to compress the skin at the sampling site.

[00011] These and other aspects, features and advantages of the invention will be understood with reference to the drawing figures and detailed description herein, and will be realized by means of the various elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following brief description of the drawings and detailed description of the invention are exemplary and explanatory of preferred embodiments of the invention, and are not restrictive of the invention, as claimed.

Brief Description of the Drawings

[00012] **FIGURE 1** shows a perspective view of an endcap for a lancing device according to an example embodiment of the present invention.

[00013] **FIGURE 2** shows a perspective view of an endcap for a lancing device according to another example embodiment of the present invention.

Detailed Description of Example Embodiments

[00014] The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this

invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Also, as used in the specification including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment.

[00015] With reference now to the drawing figures, Figures 1 and 2 show two example embodiments of endcaps 10 (corresponding reference numbers are indicated with primes in Fig. 2) for a lancing device, according to the present invention. The endcap 10 preferably comprises a first end 12 for releasable or permanent attachment to the remainder of a housing of a lancing device. Alternatively, the endcap forms an integral part of the housing of the lancing device. The endcap 10 can be adapted for use with any of a ~~variety of standard, commercially available or later developed lancing devices, by~~ appropriate configuration of coupling or attachment features of the first end 12. The second end 14 of the endcap 10 preferably defines an opening 16 through which the sharp lancet tip projects in its extended position to penetrate the skin at the intended sampling site. The endcap is preferably formed of an engineering or medical-grade polymer, plastic, or other material.

[00016] A slot 20 preferably extends across the contact face 22 of the second end 14 of the endcap, preferably through the center of the opening 16, and through at least a portion of the length of the endcap body along opposite sidewall portions thereof. The slot 20 separates the second end 14 of the endcap into opposed first and second jaws 30a,

30b. Preferably, the slot 20 does not extend through the entire length of the endcap 10, so that a base portion proximal the first end 12 of the endcap joins the first and second jaws 30a, 30b and allows the jaws to be pinched together at their free ends and resiliently return to their separated positions when released. The width of the slot 20 in the contact face 22 is preferably at least about 1 mm, to permit passage of the sharp lancet tip and to capture an amount of tissue between the jaws sufficient to stimulate a desired amount of blood-flow toward the sampling site when pinched together. The width of the slot 20 is preferably no more than about 4 to 5 mm, to prevent a standard lancet body from passing completely therethrough and being discharged from the lancing device or becoming stuck in the opening 16. More preferably, the width of the slot 20 is between about 2 mm and about 3 mm. The width of the slot 20 is preferably between about 10% to about 25%, and more preferably about 15%, of the overall diameter or outside dimension of the contact face 22.

[00017] The contact face 22 optionally includes one or more surface features, such as a raised contact ring 40, one or more ribs or protuberances, recesses, or the like, for increasing the surface area of contact with the skin around the sampling site and/or stimulating blood-flow to the sampling site. In the embodiment of Fig. 1, flats 50 are formed along the sides of the endcap body, on each jaw 30a, 30b opposite the slot 20, forming a gripping surface for the user to pinch the jaws together. In the embodiment of Fig. 2, the sides of the endcap body are ribbed or knurled to provide a gripping surface 60' on each jaw 30a', 30b' opposite the slot 20'.

[00018] In a preferred method of operation according to the present invention, the contact face 22 is placed against the skin around the sampling site, the device is triggered to lance the skin at the sampling site, and the user alternately squeezes the jaws 30a, 30b together and releases the jaws to spring back apart under the bias of the endcap material's internal resiliency. This squeezing and releasing can be repeated as necessary until the desired sample size is expressed from the sampling site wound. Optionally, a steady light pressure and/or a twisting, rocking and/or toggling motion is applied to the lancing device

against the skin around the sampling site. Pinching the jaws 30a, 30b together and releasing them to spring back apart, with the contact face 22 pressed against the skin around the sampling site, causes the skin at the sampling site to be alternately compressed and tensioned. Compressing and tensioning the skin in this manner prior to and/or during lancing may assist in directing subcutaneous blood to pool in the area of the sampling site. Compressing and tensioning the skin in this manner after lancing may further assist in expressing blood out of the wound at the sampling site, as well as prevent premature wound closure.

[00019] While the invention has been described with reference to preferred and example embodiments, it will be understood by those skilled in the art that a variety of modifications, additions and deletions are within the scope of the invention, as defined by the following claims.

What is claimed is:

1. An endcap for a lancing device, the endcap having a first end for connection to the lancing device and a second end comprising an opening for passage of a sharp tip portion of a lancet, the endcap further comprising a contact face around the opening and a slot extending through the contact face, the slot separating at least the second end of the endcap into an opposed pair of jaws.
2. The endcap of Claim 1, at least partially formed of a resilient material such that the opposed pair of jaws can be pinched toward one another and will resiliently spring back apart when released.
3. The endcap of Claim 1, further comprising a raised contact ring projecting from the contact face.
4. The endcap of Claim 1, wherein each of said opposed pair of jaws comprises a gripping surface on the sides of the endcap opposite the slot.
5. The endcap of Claim 1, wherein the slot between the opposed pair of jaws has a width of between 1 mm and 5 mm.
6. The endcap of Claim 5, wherein the slot between the opposed pair of jaws has a ~~width of between about 2 mm to about 3 mm.~~
7. The endcap of Claim 1, wherein the slot between the opposed pair of jaws has a width of between about 10% to about 25% of an outside dimension of the contact face.
8. The endcap of Claim 1, wherein the slot between the opposed pair of jaws has a width of about 15% of an outside dimension of the contact face.

9. A lancing device for collecting a sample of body fluid from a sampling site on the skin of a subject, said lancing device comprising a lancet and a housing comprising an endcap, the lancet being movable between a first position within the housing and a second position wherein at least a sharp tip portion of the lancet extends through the endcap, wherein the endcap comprises first and second opposed jaws movable between an unbiased position wherein said jaws are spaced a distance apart from one another, and a biased position wherein said jaws are squeezed toward one another.
10. The lancing device of Claim 9, wherein the endcap comprises a contact face defining an opening through which the sharp tip portion of the lancet extends when the lancet is in its second position.
11. The lancing device of Claim 10, wherein the endcap further comprises a slot extending across the contact face.
12. The lancing device of Claim 11, wherein the slot separates at least one end of the endcap into an opposed pair of jaws.
13. The lancing device of Claim 12, wherein the endcap further comprises a gripping surface on an outside portion of each of the opposed pair of jaws.
14. The lancing device of Claim 11, wherein the slot has a width of between 1 mm and 5 mm.
15. The lancing device of Claim 14, wherein the slot has a width of between about 2 mm to about 3 mm.
16. The lancing device of Claim 11, wherein the slot has a width of between about 10% to about 25% of an outside dimension of the contact face.
17. The lancing device of Claim 10, further comprising a raised contact ring projecting from the contact face.

18. The lancing device of Claim 9, wherein the endcap is at least partially formed of a resilient material to allow the endcap to flex back and forth between its unbiased and biased positions.

19. A method of lancing skin to collect a fluid sample, the method comprising:

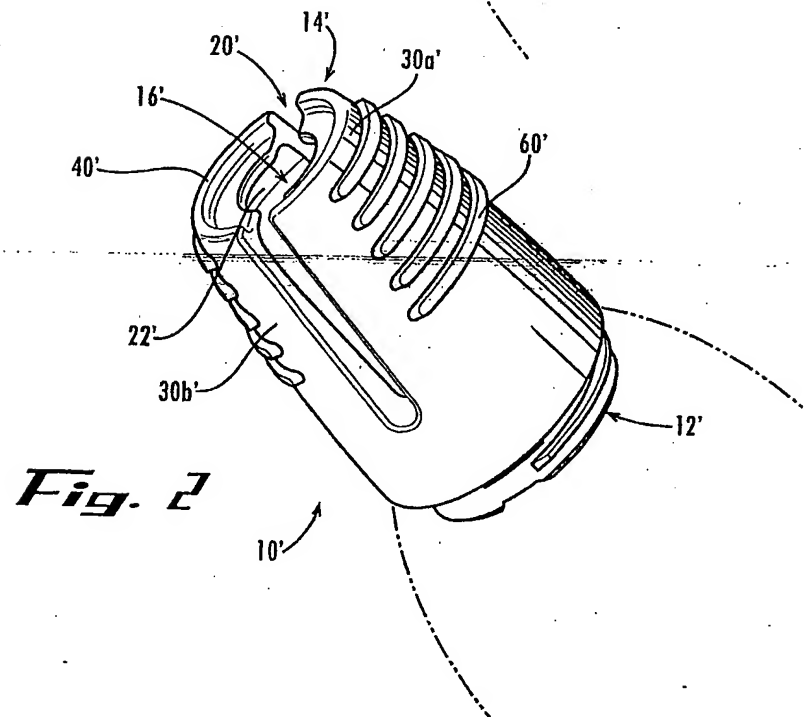
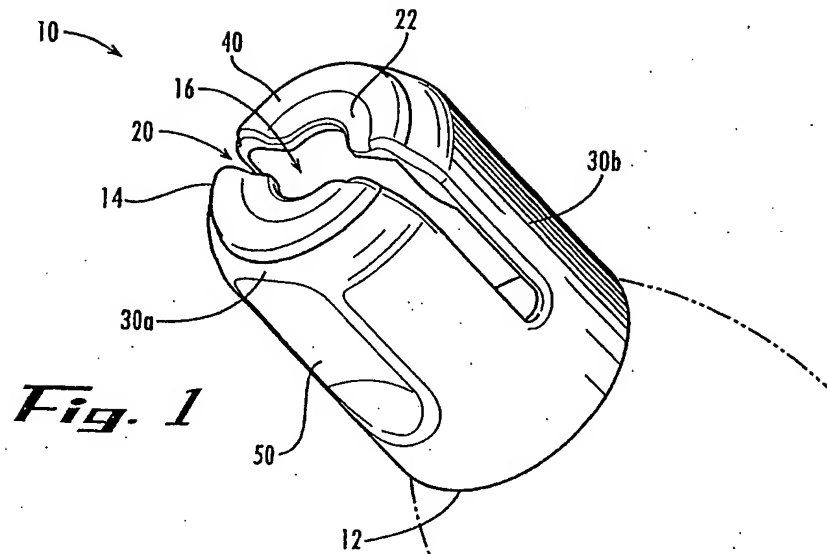
placing a contact face of a lancing device against a subject's skin at a sampling site, the contact face comprising first and second portions separated by a slot;

lancing the skin at the sampling site; and

pinching the first and second portions of the contact face toward one another to compress the skin at the sampling site.

20. The method of Claim 19, further comprising releasing the first and second portions of the contact face to move apart from one another to tension the skin at the sampling site.

1/1



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/24393

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 5/00

US CL : 600/573, 576, 583, 584; 606/181, 182

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/573, 576, 583, 584; 606/181, 182

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-----------------------|
| X | US 2002/0151920 A1 (MARSHALL et al.) 17 October 2002 (17.10.2002), Fig. 1 and 7, paragraph [0020]. | 1-2, 9-12, 18 |
| Y | | 3-4, 13, 17, 19-20 |
| X, P | US 6,752,817 B2 (FLORA et al.) 22 June 2004 (22.06.2004), column 1, lines 8-12, column 2, lines 25-36. | 1-2, 9-12, 18 |
| Y | US 6,283,982 B1 (LEVAUGHN et al.) 4 September 2001 (04.09.2001), column 9, line 67 - column 10, line 2, column 10, lines 20-31, Fig. 1. | 3, 17 |
| Y | US 4,620,549 A (NUGENT) 04 November 1986, (01.11.1986), column 3, lines 54-60, Fig. 1. | 4, 13 |
| Y | US 6,464,649 B1 (DUCHON et al.) 15 October 2002 (15.10.2002), column 7, line 48 - column 8, line 26. | 19-20 |
| A | US 6,045,567 A (TAYLOR et al.) 04 April 2000 (04.04.2000), entire document. | 1-20 |
| A | US 6,451,040 B1 (PURCELL) 17 September 2002 (17.09.2002), entire document. | 1-20 |

☐ Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

10 December 2004 (10.12.2004)

Date of mailing of the international search report

18 JAN 2005

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Max Hindenburg

Telephone No. (703) 308-0858

Sheila H. Vener
Paralegal Specialist
Tech. Center 3700

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/24393

Continuation of B. FIELDS SEARCHED Item 3:

EAST

search terms: lancet, endcap, cap, cover, resilient, compressible, flexible, slot, gap, ring, edge, grip, grasp

THIS PAGE LEFT BLANK